

## Environmental Protection Agency

## § 158.2060

19. Required if results from lower tiered mutation or reproductive studies indicate there is potential for chromosomal aberration to occur.

20. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application or consumption of treated feed.

### § 158.2060 Biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, one acute freshwater invertebrate study, plant toxicity testing, and a honeybee acute contact study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (*i.e.*, granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include: forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
850.2200	Avian dietary toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 4, 5

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 5
Nontarget Plant Testing								
850.4100	Terrestrial Plant Toxicity, Seedling emergence	R	R	NR	R	NR	TGAI, EP	5
850.4150	Terrestrial Plant Toxicity, Vegetative vigor	R	R	NR	R	NR	TGAI, EP	5
Insect Testing								
880.4350	Nontarget Insect Testing	R	R	R	R	NR	TGAI	14
Tier II								
Environmental Fate Testing								
163-1 (835.1230)	Sediment and soil adsorption/desorption for parent and degradates	CR	CR	CR	CR	NR	TGAI	6
163-1 (835.1240)	Soil column leaching	CR	CR	CR	CR	NR	TGAI	6
163-2 (835.1410)	Laboratory volatilization from soil	CR	NR	CR	CR	NR	TEP	7
161-1 (835.2120)	Hydrolysis	CR	CR	CR	CR	NR	TGAI	6
161-1 (835.4100)	Aerobic soil metabolism	CR	NR	CR	CR	NR	TGAI	6
161-2 (835.2240)	Photodegradation in water	CR	CR	CR	CR	NR	TGAI	6
161-3 (835.2410)	Photodegradation on soil	CR	NR	CR	CR	NR	TGAI	6
162-2 (835.4200)	Anaerobic soil metabolism	CR	NR	NR	NR	NR	TGAI	6
162-4 (835.4300)	Aerobic aquatic metabolism	CR	CR	CR	CR	NR	TGAI	6
162-3 (835.4400)	Anaerobic aquatic metabolism	CR	CR	NR	NR	NR	TGAI	6
880.4425	Dispenser - water leaching	CR	NR	CR	CR	NR	EP	8
Nontarget Plant								
850.4225	Seedling emergence	R	R	NR	R	NR	TGAI	9
850.4250	Vegetative vigor	R	R	NR	R	NR	TGAI	9
Tier III								
Aquatic Fauna Chronic, Life Cycle, and Field Studies								
850.1300 850.1400 850.1500	Freshwater fish/invertebrate testing	CR	CR	NR	CR	NR	TGAI	10

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1025 850.1035 850.1045 850.1055 850.1350 850.1400 850.1500	Marine/Estuarine fish/invertebrate animal testing	CR	CR	NR	CR	NR	TGAI	10
850.1950	Aquatic field fish/invertebrate testing	CR	CR	NR	CR	NR	EP	10
Terrestrial Wildlife								
850.2300	Avian Reproduction	CR	CR	NR	CR	NR	TGAI	11
850.2400	Wild mammal acute toxicity	CR	CR	NR	CR	NR	TGAI	11
850.2500	Terrestrial field testing	CR	CR	NR	CR	NR	EP	11
Beneficial Insects								
850.3040	Field testing for Pollinators	CR	CR	NR	CR	NR	TEP	12
Nontarget Plants								
850.4225 850.4250 850.4300 850.4450	Nontarget plant	CR	CR	NR	CR	NR	TGAI	13

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, physical/chemical properties, production volume, and other pertinent factors.

3. Not required for any use groups if the pesticide is highly volatile (estimated volatility  $>5 \times 10^{-5}$  atm m<sup>3</sup>/mol).

4. Preferred test species are Upland game, waterfowl, or passerine for avian acute oral toxicity studies; Upland game and waterfowl for avian dietary studies; and coldwater fish species for acute freshwater fish studies.

5. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

6. Required on a case-by-case basis when results from Tier I studies indicate adverse effects.

7. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied on land. In view of methodological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

8. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied in a passive dispenser.

9. Required to support registration of known phytotoxicants, *i.e.*, herbicides, desiccants, defoliants, and plant growth regulators.

10. Required if environmental fate characteristics indicate that the estimated environmental concentration of the pesticide in the aquatic environment is  $>0.01$  of any EC<sub>50</sub>.

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or LC<sub>50</sub> determined in the aquatic nontarget organism testing.

11. Required if either of the following criteria are met:

i. Environmental fate characteristics indicate that the estimated concentration of the pesticide in the terrestrial environment is > 0.20 the avian dietary LC<sub>50</sub> or equal to > 0.20 the avian oral single dose LD<sub>50</sub> (converted to ppm).

ii. The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian or mammalian feed.

12. Required when results of Tier I nontarget organism studies indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects. Additional insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., threatened or endangered species).

13. Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement would be determined by the results of the Tier II environmental fate studies.

14. Required depending on pesticide mode of action, method and timing of application, and results of any available efficacy data. Typically the honeybee acute toxicity guideline (guideline 850.3020) satisfies this requirement, however, additional nontarget insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., endangered species.)

## § 158.2070 Biochemical pesticides product performance data requirements.

Product performance data must be developed for all biochemical pesticides. However, the Agency typically does not require applicants to submit such efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require,

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on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

## § 158.2080 Experimental use permit data requirements—biochemical pesticides.

(a) Sections 158.2081 through 158.2084 describe the experimental use permit (EUP) data requirements for biochemical pesticides. Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) For general information on the data requirement tables, see § 158.2010(b)–(f).

## § 158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular biochemical pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Depending on the results of the required product chemistry studies, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental